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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/812,780 | 03/29/2004 | Yiwen Tang | 50623.280 | 5001 |
| 7590 Cameron Kerrigan Squire, Sanders & Dempsey L.L.P. Suite 300 One Maritime Plaza San Francisco, CA 94111 | | | EXAMINER FISHER, ABIGAIL L | |
| | | | ART UNIT 1616 | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/812,780

Applicant(s)

TANG ET AL.

Examiner

ABIGAIL FISHER

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Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 4-15 and 17-27 is/are pending in the application.
- 4a) Of the above claim(s) 12 and 25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-2, 4-11, 13-15, 17-24, and 26-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 2/8/08
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Receipt of Amendments/Remarks filed on February 8 2008 is acknowledged. Claims 3 and 16 were cancelled. Claims 1, 14 and 17 were amended. Claims 1-2, 4-15, and 17-27 are pending. Claims 12 and 25 are withdrawn as being directed to a non-elected invention. Claims 1-2, 4-11, 13-15, 17-24, and 26-27 are directed to the elected invention.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on February 8 2008 was considered by the examiner.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claims 1, 14, 16 and 24 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is **withdrawn** in light of Applicant's amendments filed on February 8 2008.

However, the rejection of claim 1 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is **maintained**. Specifically claim recites that the first and second polymer "includes". Since these polymers are chemical structures, such as an AB block copolymer, the incorporation of the phrase "includes" is indefinite

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because it is unclear what else constitutes the AB block copolymer. Are other monomers included in this chemical structure? Applicant has argued that the term "include" is a common transition term to introduce features. While this is true, this is usually associated with compositions. However, in the instant case the "includes" is referring to a specific chemical structure therefore this term causes the resulting claim to be indefinite.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue, and resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-2, 4-11, 13-15, 17-24, and 26-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Castro et al. (US Patent No. 6395326).

Applicant Claims

A medical article comprising a medical substrate and a coating deposited on the substrate. The medical article is a stent, graft, or stent-graft. The coating comprises a first polymer and a second polymer. The first polymer is poly(ethyleneglycol)-block-copoly(caprolactone). The second polymer is poly(caprolactone). The medical article additionally includes a therapeutic substance.

A medical article comprising a biologically degradable AB block copolymer and a biologically degradable polymer. The medical article is a stent, graft, or a stent graft. The biologically degradable AB block copolymer is poly(ethyleneglycol)-block-copoly(caprolactone). The biologically degradable polymer is poly(caprolactone). The article additionally includes a therapeutic agent mixed, bonded, conjugated, linked or blended with the block copolymer and/or the polymer.

A method of treating a disorder in a human comprising implanting in the human a medical article defined above wherein the disorder is selected from the group consisting

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of atherosclerosis, thrombosis, restenosis, hemorrhage, vascular dissection or perforation, vascular aneurysm, vulnerable plaque, chronic total occlusion, claudication, anastomotic proliferation for vein and artificial grafts, bile duct obstruction, ureter obstruction, tumor obstruction, and combinations thereof.

The polymers are capable at equilibrium and at room temperature of absorbing less than 5 mass % water.

Determination of the Scope and Content of the Prior Art
(MPEP §2141.01)

Castro et al. is directed to a patterned coating on a prosthesis, for example a stent (abstract). The prosthesis is coated with a composition (column 2, lines 65-66). A therapeutic substance or combinations of substances are included in the composition (column 3, lines 9-11). The polymers listed as being suitable are those that are biocompatible and include polycaprolactone (PCL), PCL-co-PEG, and combinations thereof (column 12, lines 46-67). The form of the polymers include block (column 12, line 33). The therapeutic substance or substances are dispersed in the composition of the polymer (column 13, lines 22-23).

The stent of the invention of Castro et al. is useful for a variety of medical procedures including the treatment of obstructions caused by tumors (column 21, lines 7-16).

Ascertainment of the Difference Between Scope the Prior Art and the Claims
(MPEP §2141.012)

Castro et al. does not specify using a combination of polycaprolactone and PCL-co-PEG.

Finding of Prima Facie Obviousness Rational and Motivation
(MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art to pursue known options within his or her technical grasp, specifically the polymers listed in Castro et al. as being suitable for coating a stent, resulting in the practice of the instant application with a reasonable expectation of success.

All of the claimed polymers were known in Castro et al. It would have been obvious to one of ordinary skill in the art to vary the types of polymers used to optimize the coating, resulting in the practice of the instant application with a reasonable expectation of success.

With regard to the functional limitation pertaining to absorbing less than 5 mass % water, Castro et al. discloses the same claimed polymers. Note MPEP 2112.02 (11): "Products of identical chemical composition can not have mutually exclusive properties." A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada, 911 F.2d 705,709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

With regard to the limitation that the block copolymer be an AB block copolymer. Since the copolymer listed is PCL-co-PEG, this indicates the structure of the polymer is that of AB form, a polymer of caprolactone connected to a polymer of ethylene glycol.

Response to Arguments

Applicant argues that Castro does not require the composition to include an AB block copolymer capable of absorbing about 5% or more water by mass of the AB block-copolymer nor does Castro require a second polymer include less than 5% water by mass. Applicant argues that the limitation of such a polymer having a water absorbing capacity of 5% or more by mass of the polymer would require the polymer to have an appropriate ratio of PCL block to the PEG block.

Applicant's arguments filed February 8 2008 have been fully considered but they are not persuasive. Claim 1 as currently written claims that the AB block-copolymer is **capable** of absorbing water. Capable means that it has the ability to absorb the water; it does not necessarily have to absorb water. Additionally Applicant's have argued that it is the ratio of PCL to PEG that results in the ability to absorb water. Instant claim 10 indicates that m, n, l, K, r are positive integers. A positive integer would be one. Therefore as long as an AB block polymer of PCL and PEG is present it would meet the limitation of that claim and would necessarily be able to absorb water as claimed by the Applicant.

Therefore, the rejection is maintained.

Terminal Disclaimer/Double Patenting

The terminal disclaimer filed on February 8 2008 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date

of 7229471 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Therefore, the rejection of claims 1-11, 13-24, and 26 on the grounds of nonstatutory obviousness-type double patenting over claims 1-20 of US Patent No. 7229471 is **withdrawn** in light of the filing and approval of the terminal disclaimer.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ABIGAIL FISHER whose telephone number is (571)270-3502. The examiner can normally be reached on M-Th 9am-6pm EST.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Abigail Fisher
Examiner
Art Unit 1616

AF

/Johann R. Richter/

Supervisory Patent Examiner, Art Unit 1616